CALIFIA's LUNG®

Bring Life to Simulation

CALIFIA® Lung Operators Manual

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BIOMED SIMULATION INC

Under no circumstances should this simulator system be used to guide the management of any living patient.

US Patent No. 14051442

European Patent No. 2906107

Canadian Patent No. 2887344

Singapore Patent No. 11201502855X

Chinese Patent No. ZL 201380062871X

US Patent Pending PCT/US2018/012009

CALIFIA® is in conformity with the following standards

EVS-EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

EVS-EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements

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1. Overview

The CALIFIA® Lung is a standalone product of Biomed Simulation, Inc. that can model the behavior of a human lung. It is a programmable, high fidelity simulator system designed to be used independently or connect it to any ventilator or CALIFIA® Patient Module (CPM). It is intended both as a teaching tool, and as a tool for evaluating the performance of a clinician in the conduct of a simulated clinical case.

As mentioned, CALIFIA® Lung is intended to be used independently, on its own, without the need for external devices. However, it integrates seamlessly with the CALIFIA® Simulator during ECMO or CPB. Also, a ventilator can be used to help and coordinate the ventilation of CALIFIA® Lung. It supports a 15 mm connection to any ventilator in the market.

1.1. Specifications and Requirements

Figure 1 details the minimum requirements needed for the optimal simulation running and the physical specifications of the module.

SPECIFICATIONS

LAPTOP COMPUTER (INSTRUCTOR'S PANEL)

Operating System:	MS Windows® 10
Processor (CPU):	Intel® Core™ i7 or higher
Minimum Processor Speed:	2.5 GHz multicore
RAM:	8 GB DDR4 or better
Disk Space:	10 GB
Screen Resolution:	1920 x 1080 pixels
Video ports:	HDMI
Minimum USB-A ports:	2
Network ports:	1 Ethernet 1 Wi-Fi
Touch-screen:	YES
Dimensions (typical):	10 x 1 x 15 inches
Weight (typical):	5 pounds
Power consumption (typical):	Less than 65 Watts
Operating Voltage:	100-240 V AC 50/60 Hz

CALIFIA SIMULATOR SOFTWARE

Software license type:	Perpetual
Number of activations:	2 (one included with system; second license can be activated in customer's computer).

EXTERNAL TOUCHSCREEN (LEARNER SCREEN)

Screen Resolution:	1920 1080 pixels
Screen size:	24"
Touchscreen interface:	USB-B
HDMI Port:	YES
Dimensions:	22 x 16 x 5 inches
Weight:	13 pounds
Power consumption:	35 Watts
Operating Voltage:	100-240 V AC 50/60 Hz
Operating Temperature:	0° to +40° C

CALIFIA'S LUNG MODULE

Connector:	15 mm nozzle
Dimensions:	18 x 11.4 x 5.8 inches
Weight:	24 pounds
Power consumption:	< 180 Watts
Operating Voltage:	24 V DC
Operating Temperature:	0° to +40° C
Certifications:	

WARRANTY

Term:	Califia Patient Module: 2 years parts and labor. Everything else: 1 year.

Figure 1: CALIFIA® Lung list of requirements.

2. External Connections:

2.1. Data and Power Connections.

Connect the power adapter to the connector labeled 24 VDC. The Ethernet cable goes from your laptop and attaches to the Ethernet terminal. The Power Switch lights up green when the unit is powered on as shown in Figure 2.

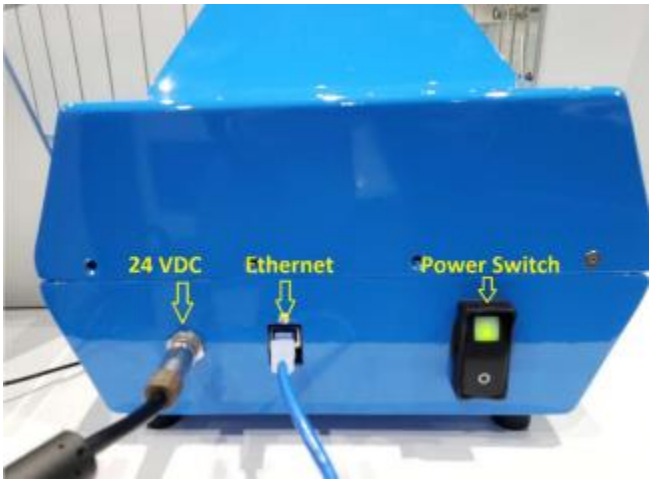

Figure 2: Lung Simulator Module Connectivity.

2.2. Connection to Ventilator.

The CALIFIA® Lung Module is equipped with a 15 mm connector. To connect it to a mechanical ventilator, use standard ventilator tubing, Figure 3. Review Section 3 of this manual for detailed instructions on operating the CALIFIA® Lung, including guidance on when to connect the ventilator and initiate ventilation.

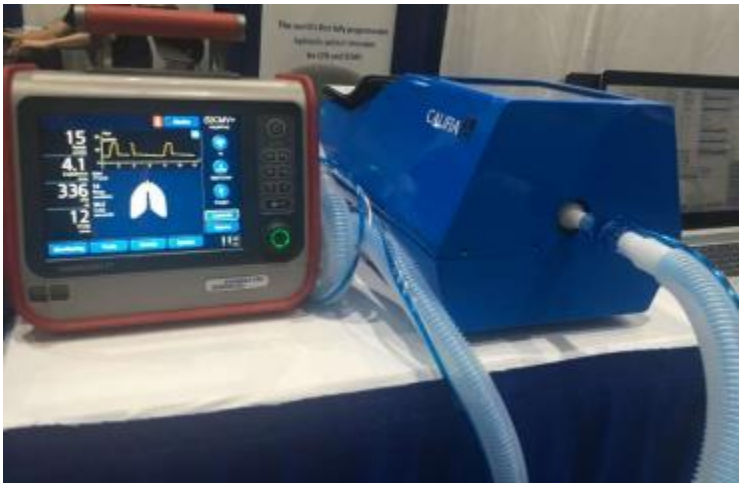

Figure 3: CALIFIA® Lung Connected to Hamilton Medical's T1 ventilator.

3. Operation.

In this section, the device's independent operation is explained, together with how it can be used in conjunction with a ventilator (CMV mode).

3.1. CALIFIA® Lung Section in Instructor's Panel.

The **CALIFIA® Lung** tab, Figure 4, is available when the Lung Module is recognized by the CALIFIA® Simulator software. The elements in this section are dictated by the **Lung Mode**.

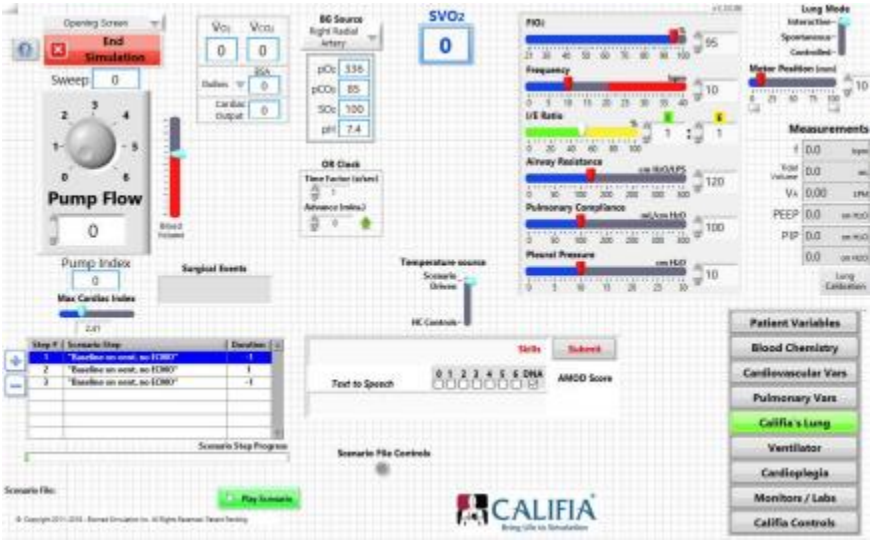

Figure 4: VA ECMO - CALIFIA® Lung Section.

3.2. Interactive Mode.

The Lung Module defaults to **Interactive** mode. This mode is not part of physiology, and its use is limited to testing the device, as it allows to control and modify all the parameters. In this way, the **Motor Position (mm)** slider can be used to place the motor at an exact position.

- Position 0 mm (zero) is the linear motor fully retracted representing the maximum lung volume allowed.
- Position 100 mm is the linear motor fully extended therefore the smallest lung volume possible.

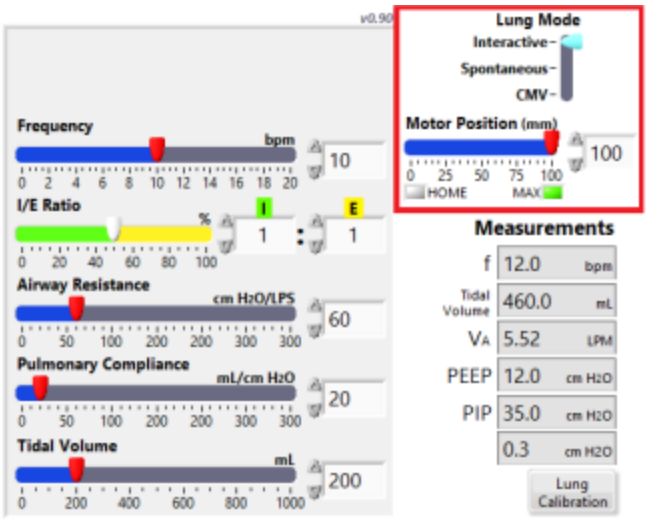

Figure 5: CALIFIA® Lung section - Interactive mode.

3.3. Spontaneous Mode.

In this mode, the Lung Module spontaneously breathes and can be assisted with a Ventilator. Since an actual ventilation device is used, the CALIFIA® Simulator virtual Ventilator is simplified to only the FiO2 dial becoming available.

The following parameters will affect the breathing quality:

- **FiO2** (%) slider is used to match the Ventilator's FiO2 setting.
- **Frequency** (bpm) slider dictates breath rate in breaths per minute.
- **I/E Ratio** specifies the complementary inspire and expire fractions. These can either be set using the slider or numerically entered.
- **Airway Resistance** (cmH2O/LPS) specifies resistance to flow in the respiratory tract. Although this parameter is shown in Spontaneous mode, it's only useful in CMV mode, see section 3.4.
- **Pulmonary Compliance** (mL/cmH2O) – it refers to the ability of our Lung Device to stretch and expand. This parameter is also available under **Pulmonary Vars** tab.
- **Tidal Volume** (mL) is the target volume displacement; used as the amplitude driving the Lung Module's spontaneous breathing cycle.

3.4. CMV Mode

CMV is Controlled Mandatory Ventilation. In this mode, CALIFIA® Lung is fully controlled by a ventilator.

The **I/E Ratio** turns into an indicator, reporting inspiration and expiration fractions as measured. Both **Frequency** and **Tidal Volume** sliders are hidden, since these parameters are dictated by the ventilator.

To adjust the breathing quality of Califia Lung, the **Airway Resistance** and **Pulmonary Compliance** parameters are available for customization.

3.5. Measurements.

When CALIFIA® Lung is either spontaneously breathing or controlled with a ventilator; the following measurements are carried out and displayed as follows, Figure 6:

- **f** is the measured breathing rate, expressed in breaths per minute (*bpm)*.
- **Tidal Volume** is the volume of air, measured in *mL*, inhaled or exhaled in each breath cycle.
- **Alveolar Ventilation** (*LPM*) is the difference between **Tidal Volume** and **Dead Space** over a minute.
- **PEEP** and **PIP** correspond to the minimum and maximum pressures, respectively, measured during a breath cycle.
- The last pressure indicator is the instantaneous pressure, reported continuously by the Lung Module.

Note: When **Lung Mode** is **Interactive**, these measurements display values corresponding to the virtual ventilator.

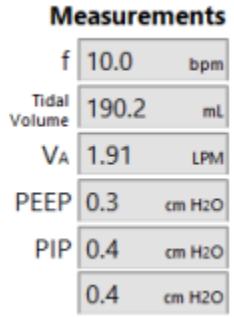

Figure 6: CALIFIA® Lung Measurements cluster

3.6. Lung Simulator Module Parameters Available.

Units	Range	
	Min	Max

Pulmonary Compliance	mL/cmH2O	5	200
FiO2	%	21	100
Breath Frequency	bpm	0	250
Airway Resistance	cmH2O/LPS	10	200
Pleural Pressure	cmH2O	0	30

Table 1: Scenario File Parameters Relevant to the Lung Simulator Mode.

The ranges in Table 1 are an estimate of what the device would support. It may be changing according to the ventilator settings and other external factors.

4. The lung Panel

The **Lung Panel** button launches **CALIFIA® Lung Panel**, Figure 7.

It has three tabs:

- **Displays**: it displays various relevant lung traces.
- **Calibrations**: for calibrating the different sensors available within the Lung Module.
- **Remote Panel**: placeholder tab reserved for future development.

4.1. Lung Panel Displays tab

The **Displays** tab presents two types of traces:

- Time-series for Volume, Pressure & Flow.
- Cyclical relations between Volume Flow as well as Volume – Pressure.

The **PV Loops** field specifies the number of breath cycles to display in both time-series and cyclical plots, with a default setting of 5 loops.

The **ActiveExp** (%) is a miscellaneous parameter specifying the portion of the expiration time the stepper motor is moving. This is used to allow for a rest period while CALIFIA® Lung is operating in **Spontaneous** mode.

Finally, the image and the indicator in bottom right of panel animate the process of inspiring and expiring.

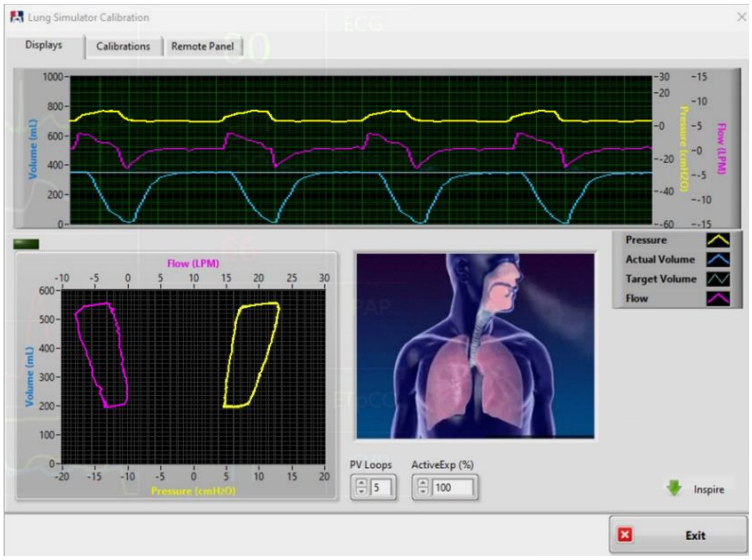

Figure 7: Lung Panel Displays.

4.2. Lung Panel Calibrations tab

The calibration parameters are displayed along the left side, Figure 8. These are saved with the Lung Module and can be manually edited. The recommended method to calibrate sensors is to perform a two-point calibration for any of these pairs. Press the **Enable Calibration** button to access this capability then select the calibration tab of interest.

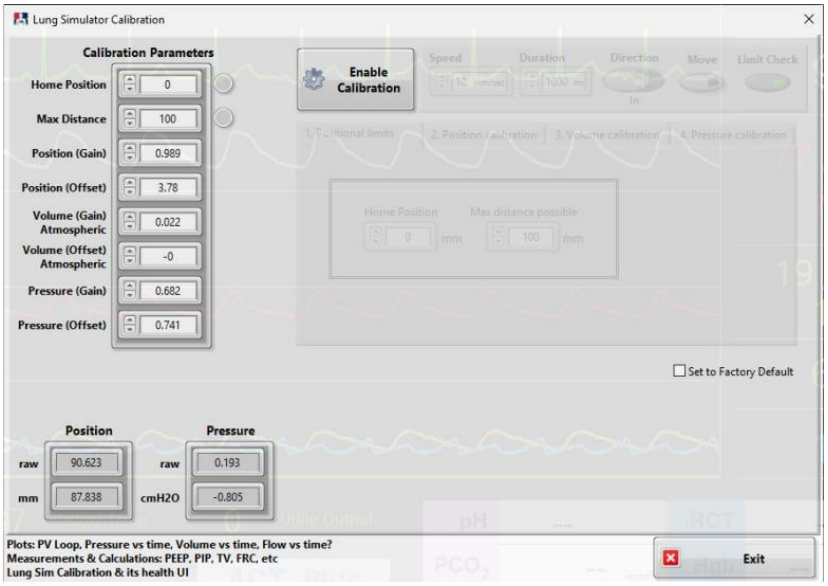

Figure 8: Lung Calibration Panel.

4.2.1. Positional Limits

Specify the **Home Position** and the **Max distance possible** in mm, Figure 9. It is recommended not to change from their factory values (0 & 100 mm respectively).

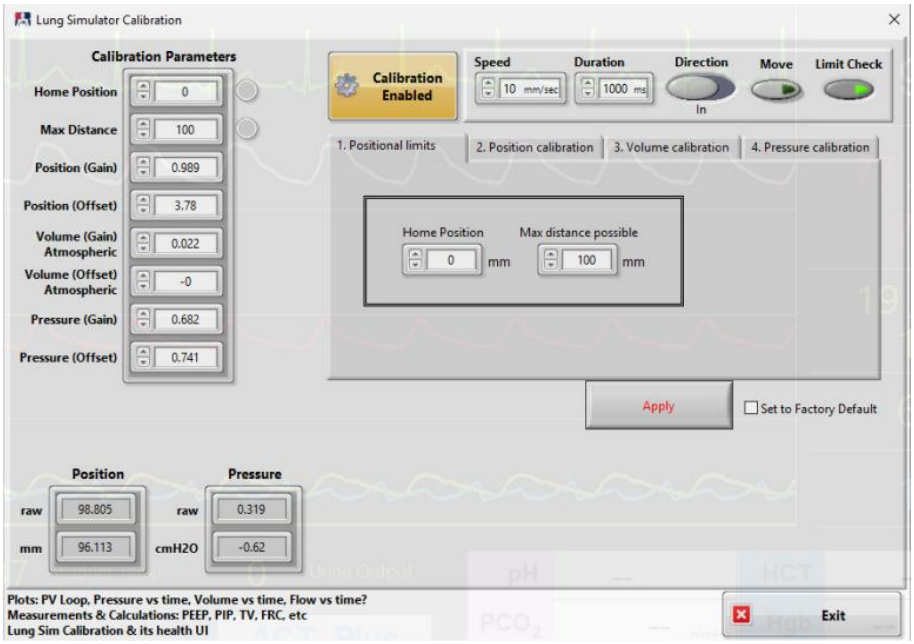

Figure 9: Positional limits tab.

4.2.2. Position Calibration

The objective is to place positional markers for two distance values of the linear motor driving the lung, Figure 10. To achieve optimal calibration, it is best to maximize the distance between these two markers; therefore, the default is to use the home position and the maximum distance available.

To move the motor, the airlet is not obstructed, and then use the controls to the right of the **Calibration Enabled** button. A description of each of these elements follows:

- **Speed**: the linear motor has a range of 100 mm. Therefore, 10 mm/sec would take the motor 10 seconds to traverse the entire length of displacement.
- **Duration:** the block of time to actuate the linear motor. If 1000 msec the motor will move for one second when requested.
- **Direction**: this control determines the motor's direction of motion. **In** retracts the linear motor, while **Out** moves it outward. Move Press this button once for each move request.

- **Limit Check**: turning this button off disables the ability to check when the motor has reached either the home position or its maximum position. Note: Turning this off can damage the motor or the bellows. **Only use this feature under the guidance of Biomed Simulation personnel.**

Steps to perform a two-point **position calibration**:

1. Move motor to Position 1 (i.e.: 0 mm) then press **Position 1** box.
2. Move motor to Position 2 (i.e.: 100 mm) then press **Position 2** box.
3. Press **Apply** button to save the new values.
4. After completing a **position calibration** process, set **Limit Check** to **ON**.

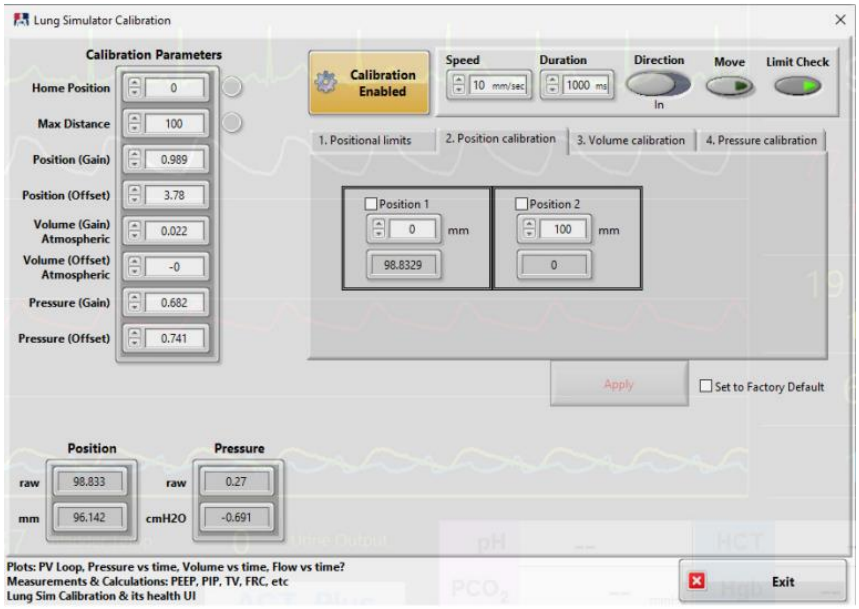

Figure 10: Position calibration tab.

4.3. Volume Calibration

This calibration relates the Lung volume under atmospheric pressure to two position markers, Figure 11. It ensures that the size of bellows is accurately matched. This calibration would be necessary if the bellows are replaced with a different size.

Steps to perform a two-point **volume calibration**:

1. Set corresponding motor position and volume in the bellows. For instance, when motor is fully stretched (i.e.: 100 mm), Volume would be 0 L.
2. The second value can be when motor is fully retracted (i.e.: 0 mm), Volume would correspond to the maximum volume of the bellows at atmospheric pressure.

3. Press **Apply** button to save new values.

Note: No motor movements are needed to complete the **volume calibration**.

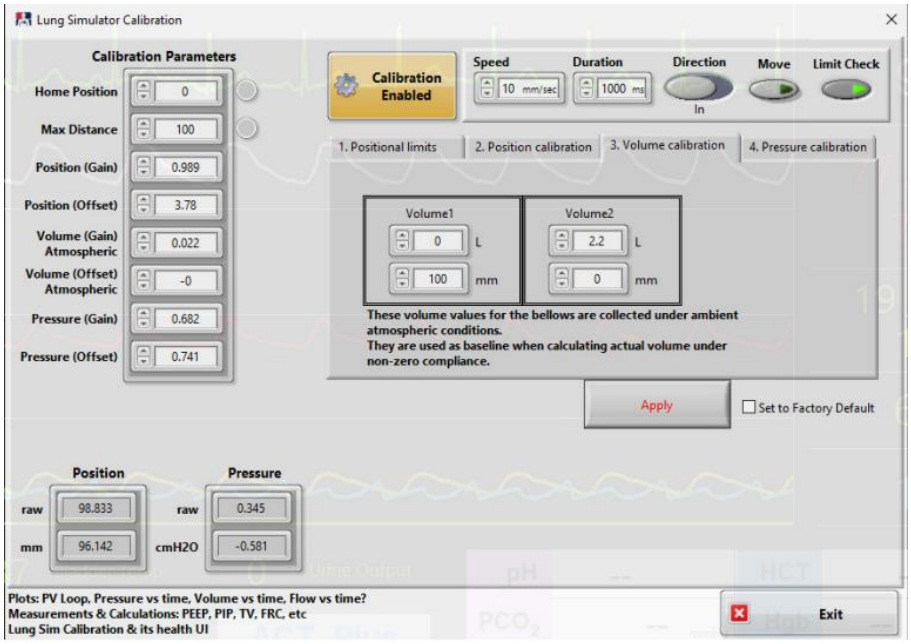

Figure 11: Volume calibration tab.

4.4. Pressure Calibration

For the two-point pressure calibration, one pressure value is atmosphere (i.e.: 0 cmH2O) press **Pressure 1** box; then apply a known and constant pressure, say 40 cmH2O, press **Pressure 2** box, Figure 12.

Press **Apply** button to accept the two values and calculate the pressure calibration values.

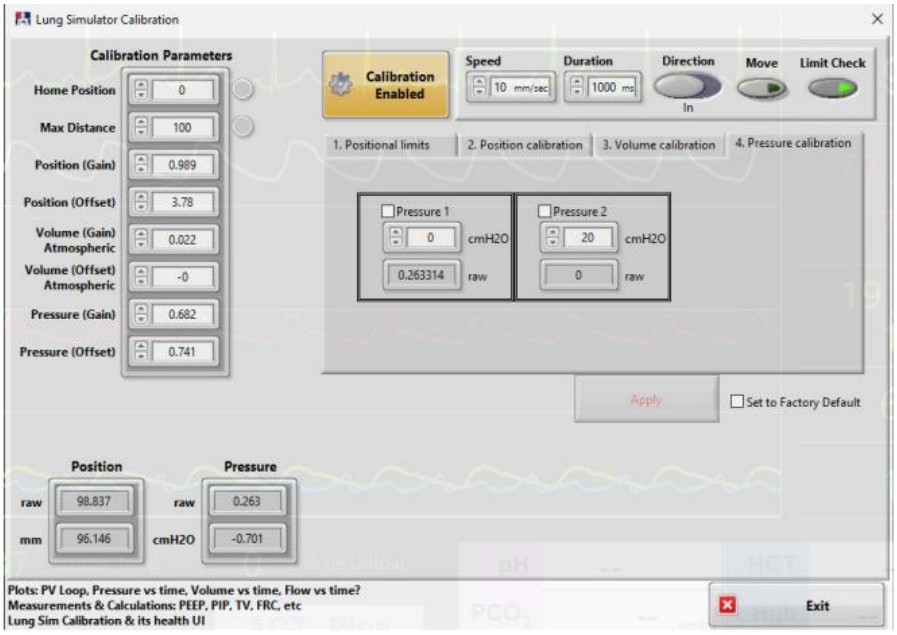

Figure 12: Pressure calibration tab.

5. CALIFIA® Patient Module and CALIFIA® Lung together

CALIFIA® Lung integrates with the CPM, Figure 13. This setup involves a LAN switch connecting the CPM and Lung Module, the rest refers to the usual setup followed for CPM and Lung modules independently. Detailed instructions for this configuration can be found in the CALIFIA® Simulation Operator's Manual.

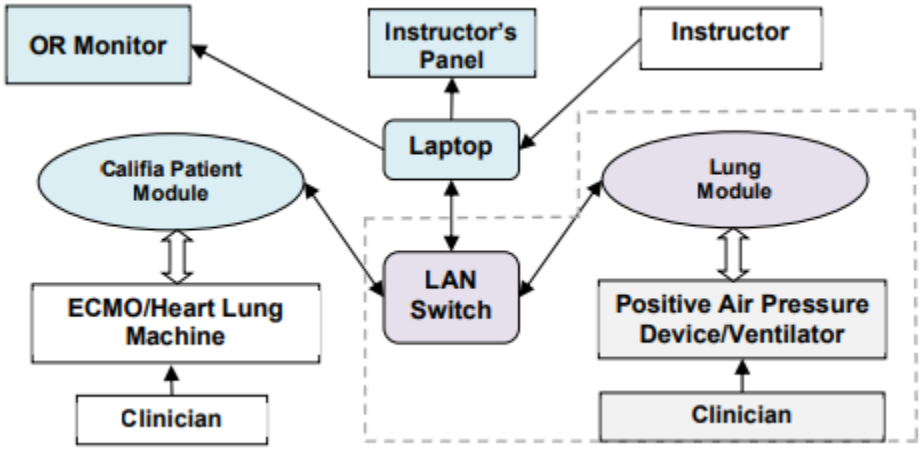

Figure 13: CALIFIA® and Lung Simulator Components.

5.1. Available Therapies

Table 2 shows the Lung Module supported in all the CALIFIA® Simulator therapies.

	CPB	CPB (Sim)	VA ECMO	VA ECMO (Sim)	VV ECMO	VV ECMO (Sim)	LHB	LHB (Sim)
CPM+LM	✓		✓		✓		✓	
LM only	✓	✓	✓	✓	✓	✓	✓	✓

CPM: Califia Patient Module
LM: Lung Module

Table 2: Lung Simulator Support with CALIFIA® Simulator Therapies.

For the most effective training experience, both the Lung Module and the CPM should be integrated into the simulated clinical scenario.

6. IP Address and Software Configuration

The first column in Table 3 lists the IP addresses for all components connected to the LAN Switch.

	IP address	Software Version
Laptop	100.100.100.25	1.80.00 or newer
Califia Patient Module	100.100.100.13	2.80 (firmware)
Lung Module	100.100.100.17	1.00 (firmware)

Table 3: Fixed IP addresses & minimum software versions required.

The last column in Table 3 lists the minimum versions of the CALIFIA® Simulator software and firmware required to support both of these devices. Please contact Biomed Simulation, Inc. for the latest software or assistance with completing software updates.

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